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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/784,222	10/28/91	WESTBROOK	C ARCD:010/UCH

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EXAMINER

FREDMAN, J

ART UNIT	PAPER NUMBER
1634	33

DATE MAILED: 07/20/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

07/784,222

Applicant(s)

Westbrook

Examiner

Jeffrey Fredman

Group Art Unit

1634



☒ Responsive to communication(s) filed on Jun 15, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 and 5-35 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 and 5-35 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 21

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by “fluorescent labels comprise digoxigenin-11-dUTP and biotin-11-dUTP” since these compounds are not, themselves, fluorescent. These compounds are haptens which are used to bind fluorescent labels.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-10, 12-21, 23, 24, 26, 28, 31-33, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Tkachuk et al (Science (October 26, 1990) 250:559-562).

Tkachuk teaches a composition comprising at least two probes, which are either pEM12, or c-H-abl (page 560, column 1) which are distinguishably labeled with digoxigenin labeled pEM12 (BCR probe) which is then bound to rhodamine and biotin labeled c-H-abl (ABL probe) which is then bound to fluorescein, where the probes hybridize to the two sides of a BCR-ABL junction (page 560, column 1 and page 561, figure 2). Tkachuk further teaches that a fusion gene

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is expressed (page 559, column 2), that the translocation breakpoints are t(9;22)(q11;q34) (abstract), that the sample may include human peripheral blood or bone marrow (abstract) in interphase and that the probes hybridize in situ (page 561, figure 2). The pEM12 probe hybridizes to an exon of BCR and the c-H-abl probe hybridizes to the last exon of the ABL gene.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 11, 22, 25, 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tkachuk et al in view of Rubin et al (Proc. Natl. Acad. Sci. (1988) 85:2795-2799) and further in view of Stratagene catalog (1988) page 39.

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Tkachuk teaches the use of dual probes and the use of the pEM12 and c-H-abl probe as discussed above. Tkachuk does not teach the use of the MSB-1 probe directed towards the first exon of the BCR gene. Tkachuk also does not teach placing the reagents of use into a kit.

Rubin teaches the use of a BCR exon I probe (page 2797, figure 2) for detection of acute lymphoblastic leukemia.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the probes of Tkachuk with the probes of Rubin since Rubin shows the effective use of this BCR exon I probe in detecting ALL. Further motivation is provided by Rubin who notes "These results demonstrate that the breakpoint has occurred within the BCR gene between exon 1 and the bcr (page 2797, column 2)". This statement motivates the use of a BCR exon I probe since only such a probe would have detected BCR in this patient. With regard to the specific MSB-1 probe, the Rubin probe is structurally and functionally identical to it (and may be the same probe. It would have been obvious to the ordinary artisan to find structural or functional equivalents to the BCR exon I probe such as slightly longer or shorter probes or probes with more convenient restriction sites. The court stated in *In Re Deuel* that

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar

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properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (34 USPQ 1210, 1214)".

The claimed MSB-1 probe simply represent structural homologs of Rubin's BCR exon I probe, and the MSB-1 probe is selected from the same exon identified by Rubin as desirable for probe synthesis. The level of skill in the art is such that a biochemist of ordinary skill would attempt and expect to succeed in obtaining alternate compounds, specifically, different BCR exon I probes, with improved properties. For these reasons, the claimed probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

Further, it would have been *prima facie* obvious to combine the probes of Tkachuk and Rubin into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

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Conclusion

6. Because this action rejects claims which were previously indicated as allowable, the action is non-final.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1634

July 16, 1998